Serial No.: 10/760,089 Case No.: E1002Y

Page

#### **REMARKS**

# **Notice of Non-Compliant Amendment**

The Examiner noted that the treatment of Latin names appearing in claims 5, 6, 8 and 9 has changed from italics to underlined and that this appears to be a claim amendment. If so, the claims would be improperly designated as Original.

Applicant apologizes for this change in formatting. The claims presented in the accompanying claim listing conform to the original use of italics in claims 5, 6 8 and 9. Thus, the issue of whether the claims were amended is believed to be moot.

### **Amendment**

Applicant herein amends the Application to Withdraw claims 10-13 without prejudice to the presentation of subject matter within these claims in this, divisional or continuing applications.

### **Requirement for Restriction**

Applicant hereby elects to prosecute the claims of Group I with traverse. Applicant respectfully notes that the non-elected claims represent methods of use of and methods of making of the compositions of the claims of Group I. The claims of Groups II, III and IV are linked by a unifying feature, the compositions of the claims of Group I. Therefore, there should be no greater burden on the Examiner to search and examiner the non-elected claims and the claims of Group I together.

The Examiner noted that the Claims have a unifying special technical feature a "conjugate comprising poly-D-gamma glutamic acid of over 100 kDa linked to an immunogenic carrier protein." The Examiner then contends that the feature is not an appropriate unifying feature under PCT Rule 13.2 because the feature is already disclosed in the art, citing Prodhomme *et al.*, (In: *Abstracts of the 219<sup>th</sup> ACS National Meeting*. March 26-30, 2000, San Francisco, CA. #133 American Chemical Society, Washington, DC). Applicant respectfully disagrees.

Serial No.: Case No.:

10/760,089 E1002Y

Page

5

The Prodhomme abstract merely states that poly –D- gamma glutamic acid is "an unusual gamma-linked polypeptide of high molecular weight (150-200Kda) isolated from *Bacillus licheniformis*". The abstract does not state that the authors purified poly-D-gamma glutamic acid that was above 100 kDa, nor that the polypeptide over 100kDa was linked to an antibody. The abstract is silent as to the size of the polypeptide actually used in the conjugate. Further, the sentence quoted above can be read as simply describing the native polypeptide as it is produced by *Bacillus*.

Applicant does not see the abstract as describing the conjugates of the present claims. Therefore, the conjugates are believed to be an appropriate feature under PCT Rule 13.2 and that all the claims should be examined together.

Applicant respectfully requests that the requirement for restriction be withdrawn to allow all the claims to be examiner together.

The Examiner has stated that the claims recite species that lack unity stating that they do not share antigenic or immunospecific characteristics. Applicant disagrees. With respect to the carrier proteins, Applicant contends that the carrier proteins recited are well known in the art as antigenic, immunostimulatory proteins that are suitable for use as carrier proteins. Therefore, they may all be grouped together as proteins often useful in stimulating immune responses against epitopes attached to them. Therefore these proteins do share common features that make it appropriate to examine them together. However, should the Examiner maintain the requirement, Applicant elects the OMPC protein as the elected carrier protein as recited in claims 5, 6 and 8. If the Examiner maintains the requirement Applicant will amend the claims accordingly.

The Examiner has stated that the claims recite species that lack unity stating that they do not share antigenic or immunospecific characteristics. Applicant disagrees. With respect to the additional antigen proteins, Applicant contends that the additional antigens recited are well known in the art as antigenic, immunostimulatory proteins that are suitable for use as vaccines. Moreover, the patentability of the claim is predicated not on the presence of additional antigens in a multivalent vaccine, but on the conjugates of the present invention. Therefore, they may all be grouped together as antigens often useful in providing a multivalent vaccine. Therefore they

Serial No.:

10/760,089 E1002Y Case No.:

Page

do share common features that make it appropriate to examine them together. However, should the Examiner maintain the requirement, Applicant elects the Haemophilus influenzae antigen recited in claim 9. If the Examiner maintains the requirement Applicant will amend the claims accordingly.

# **CONDITIONAL PETITION**

Applicant hereby makes a Conditional Petition for any relief available to correct any defect in connection with this filing, or any defect remaining in this application after this filing. The Commissioner is authorized to charge deposit account 13-2755 for the petition fee and any other fee(s) required to effect this Conditional Petition.

Respectfully submitted,

Michael D. Yablonsky, Ph.D.

Reg. No. 40,407

Attorney for Applicant(s)

MERCK & CO., INC.

P.O. Box 2000

Rahway, New Jersey 07065-0907

(732) 594-4678

DATE 07 September 2008